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EXAMINER
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LEE, SHUN K

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2884

DATE MAILED: 11/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/649,677

Applicant(s)

ABEL ET AL.

Examiner

Shun Lee

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 August 2003 and 06 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☒ Certified copies of the priority documents have been received in Application No. 10/000,957.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 16 September 2005 has been entered.

### ***Specification***

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 41-55 and 60-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 41-55 and 60-62 provides for the use of a sensor platform, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it

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merely recites a use without any active, positive steps delimiting how this use is actually practiced.

***Claim Rejections - 35 USC § 101***

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 41-55 and 60-62 are is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, *i.e.*, results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 2, 4-10, 12-17, 19-27, 29-50, and 53-62 are rejected under 35 U.S.C. 102(b) as being anticipated by Neuschäfer *et al.* (WO 96/35940).

In regard to claims **1, 23, 36, 56, 58, and 59**, Neuschäfer *et al.* disclose (Figs. 1c and 6) an analytical system for the determination of one or more analytes in at least one sample by luminescence detection, said analytical system comprising:

- (a) at least one excitation light source (13) operable to emit excitation light;
- (b) a sensor platform (8; for a simultaneous determination of at least one luminescence from a plurality of measurement areas) comprising:
  - (b1) a plurality of laterally separated measurement areas (1), wherein a density of said plurality of laterally separated measurement areas is 0.4 to 40,000 (e.g., at least 16) measurement areas per square centimeter (*i.e.*, each measurement area is 5  $\mu\text{m}$  to 5 mm width by 0.5 to 50 mm length or equivalently  $2.5 \times 10^{-5} \text{ cm}^2$  to  $2.5 \text{ cm}^2$ ; last paragraph on pg. 12 to fourth paragraph on pg. 13);
  - (b2) an optical film waveguide (first two paragraphs on pg. 1) comprising a waveguiding layer (*i.e.*, a first optically transparent layer), a substrate (*i.e.*, a second optically transparent layer) having a lower refractive index than said first optically transparent layer, said first optically transparent layer being on said second optically transparent layer, and a grating structure (3 and/or 3') being operable to incouple the excitation light to said plurality of laterally separated measurement areas (1), wherein said plurality of laterally separated measurement areas (1) are located on said first optically transparent layer, said grating structure (3 and/or 3') is continuously modulated (third paragraph on pg. 8; third paragraph on pg. 17) over a complete of said plurality of laterally separated measurement areas (1), and said grating structure (3 and/or 3') is operable to prevent a cross-talk (fourth paragraph on pg. 7) of luminescence generated in any one measurement area of said plurality of

- laterally separated measurement areas (1), and coupled back into said first optically transparent layer to any other measurement area of said plurality of laterally separated measurement areas; and
- (b3) at least one recognition element (second paragraph on pg. 18) immobilized in said plurality of laterally separated measurement areas (1), said at least one recognition element being operable to assist in a qualitative or quantitative determination of the one or more analytes in the at least one sample in contact with said plurality of laterally separated measurement areas (1);
- (c) at least one detector (14) operable to collect light emanating from one or more of said plurality of laterally separated measurement areas (1) on said sensor platform (8); and
- (d) supply means (10, 11; second paragraph on pg. 26) for supplying the at least one sample in contact with said plurality of laterally separated measurement areas (1) on said sensor platform (8).

In regard to claim 2 (which is dependent on claim 1) and claim 57 (which is dependent on claim 56), Neuschäfer *et al.* also disclose (Figs. 2-5) that said plurality of laterally separated measurement areas are split into at least two laterally separated segments, each of said laterally separated segments comprising at least two of said plurality of laterally separated measurement areas.

In regard to claim 4 which is dependent on claim 1, Neuschäfer *et al.* also disclose (fourth and fifth paragraphs on pg. 15) an intermediate layer (*i.e.*, a third optically transparent layer) in contact with said first optically transparent layer, wherein

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said third optically transparent layer has a lower refractive index than said first optically transparent layer and said third optically transparent layer has a thickness of  $\gg 100$  nm and not thicker than 0.01 mm (*i.e.*, 5 nm - 10,000 nm) and is located between said first optically transparent layer and said second optically transparent layer.

In regard to claim **5** which is dependent on claim 1, Neuschäfer *et al.* also disclose (fifth through seventh paragraphs on pg. 19; last paragraph on pg. 20) an adhesion-promoting layer with a thickness of less than 50 nm (*i.e.*, less than 200 nm) deposited on said first optically transparent layer, said adhesion-promoting layer operable to immobilize one of biological elements, biochemical elements and synthetic recognition elements, wherein said adhesion-promoting layer comprises chemical compounds from a group consisting of silanes, epoxides, and self-organized functionalized monolayers.

In regard to claim **6** which is dependent on claim 1, Neuschäfer *et al.* also disclose (eighth paragraph on pg. 19) that said plurality of laterally separated measurement areas are generated by laterally selective deposition of at least one of biological elements, biochemical elements and synthetic recognition elements on said sensor platform, by one of jet spotting, mechanical spotting, micro contact printing, and fluidic contacting said plurality of laterally separated measurement areas with said at least one of biological elements, biochemical elements and synthetic recognition elements supplied in parallel or by crossed micro channels, upon application of one of pressure differences, electric potentials and electromagnetic potentials.

In regard to claim **7** which is dependent on claim 6, Neuschäfer *et al.* also disclose (fourth paragraph on pg. 21) that said at least one of biological elements, biochemical elements and synthetic recognition elements, components of a group consisting of nucleic acids and nucleic acid analogues, antibodies, aptamers, membrane-bound and isolated receptors, ligands of the membrane-bound and isolated receptors, antigens for antibodies, histidine-tag components, and molecular imprints hosted in cavities generated by chemical synthesis, are deposited as whole cells or cell fragments.

In regard to claim **8** which is dependent on claim 6, Neuschäfer *et al.* also disclose (eighth paragraph on pg. 19) compounds, which are chemically neutral towards the at least one analyte, deposited between said plurality of laterally separated measurement areas in order to minimize nonspecific binding or adsorption.

In regard to claim **9** which is dependent on claim 1, Neuschäfer *et al.* also disclose (last paragraph on pg. 12 to fourth paragraph on pg. 13) that 2 to 1000 (*i.e.*, up to 100,000) of 5  $\mu\text{m}$  to 5 mm width by 0.5 to 50 mm length measurement areas are provided in a 2-dimensional arrangement (see Figs. 1-5) and thus a single measurement area has an area of 0.0025  $\text{mm}^2$  to 250  $\text{mm}^2$  (*i.e.*, 0.001  $\text{mm}^2$  - 6  $\text{mm}^2$ ).

In regard to claim **10** which is dependent on claim 1, Neuschäfer *et al.* also disclose (last three paragraphs on pg. 16 and first seven paragraphs on pg. 17) that said grating structure is one of a diffractive grating with a uniform period and a multidiffractive grating.



In regard to claim **12** which is dependent on claim 1, Neuschäfer *et al.* also disclose (second paragraph on pg. 15) that the substrate (*i.e.*, said second optically transparent layer) comprises one of quartz, glass or transparent thermoplastic.

In regard to claim **13** which is dependent on claim 1, Neuschäfer *et al.* also disclose (first paragraph on pg. 16) that said first optically transparent layer has a refractive index that is higher than 2.

In regard to claim **14** which is dependent on claim 1, Neuschäfer *et al.* also disclose (second paragraph on pg. 16) that said first optically transparent layer comprises one of  $\text{TiO}_2$ ,  $\text{ZnO}$ ,  $\text{Nb}_2\text{O}_5$ ,  $\text{Ta}_2\text{O}_5$ ,  $\text{HfO}_2$ , or  $\text{ZrO}_2$ .

In regard to claim **15** which is dependent on claim 1, Neuschäfer *et al.* also disclose (fourth paragraph on pg. 16) that said first optically transparent layer has a thickness of between 40 and 1,000 nm (*i.e.*, between 40 and 300 nm).

In regard to claim **16** which is dependent on claim 1, Neuschäfer *et al.* also disclose (fifth paragraph and also the last paragraph on pg. 16) that said grating structure has a period of 200 nm - 1000 nm and a modulation depth of 3 nm - 60 nm (*i.e.*, 3 nm - 100 nm).

In regard to claim **17** which is dependent on claim 1, Neuschäfer *et al.* also disclose (third and fourth paragraphs on pg. 4) that coupling efficiency of the grating coupler depends on the grating coupler modulation depth (with reference to Proc. SPIE 2068:313-325) and that coupling efficiency should be adequate so as to be able to measure luminescence. Thus inherent in an adequate coupling efficiency (that depends on the grating coupler modulation depth) is a coupling efficiency and is less than 100%

(i.e., incoupling and outcoupling of excitation light and/or backcoupled luminescence light is incomplete). Neuschäfer *et al.* further disclose (seventh paragraph on pg. 17) that the guided radiation intensity falls and the length at which the guided radiation intensity has fallen to  $I_0/e$  is  $X_{1/e}$ . Thus it is inherent in guided radiation which has fallen to  $I_0/e$  at a distance of  $X_{1/e}$  that the extent of the losses along the guided radiation propagation direction (i.e., distance  $X_{1/e}$ ) determines a gradient of the guided radiation intensity (i.e., at least one of intensity of guided excitation light and generated luminescence light) in the waveguiding layer (i.e., first optically transparent layer) within at least one measurement area of said plurality of laterally separated measurement areas and across several measurement areas of said plurality of laterally separated measurement areas.

In regard to claim **19** which is dependent on claim 1, Neuschäfer *et al.* also disclose (seventh paragraph on pg. 17) that the guided radiation intensity falls and the length at which the guided radiation intensity has fallen to  $I_0/e$  is  $X_{1/e}$ . Thus it is inherent in a guided radiation which has fallen to  $I_0/e$  at a distance of  $X_{1/e}$  that the extent of the losses along the guided radiation propagation direction (i.e., distance  $X_{1/e}$ ) determines a gradient of the guided radiation intensity (i.e., at least one of intensity of guided excitation light and generated luminescence light) in the waveguiding layer (i.e., first optically transparent layer) within at least one of measurement area of said plurality of laterally separated measurement areas and across several measurement areas said plurality of laterally separated measurement areas.

In regard to claim **20** which is dependent on claim 16, Neuschäfer *et al.* also disclose (seventh paragraph on pg. 16) that a ratio of the modulation depth to a thickness of said first optically transparent layer is equal or smaller than 0.2.

In regard to claim **21** which is dependent on claim 1, Neuschäfer *et al.* also disclose (eighth and ninth paragraphs on pg. 16) that said grating structure is one of a relief grating with a rectangular, triangular or semi-circular profile and a phase or volume grating with a periodic modulation of a refractive index in said first optically transparent layer which is essentially planar.

In regard to claim **22** which is dependent on claim 1, Neuschäfer *et al.* also disclose (last paragraph on pg. 39) one of optically recognizable marks and mechanically recognizable marks operable to simplify adjustments in an optical system, or for connection to sample compartments as part of an analytical system.

In regard to claim **24** which is dependent on claim 23, Neuschäfer *et al.* also disclose (last two paragraphs on pg. 7) that said at least one excitation light source launches the excitation light to said plurality of laterally separated measurement areas in an arrangement of direct or transmission illumination.

In regard to claim **25** which is dependent on claim 23, Neuschäfer *et al.* also disclose (second paragraph on pg. 29) that said at least one detector also collects luminescence light outcoupled by said grating structure.

In regard to claim **26** which is dependent on claim 23, Neuschäfer *et al.* also disclose (last paragraph on pg. 16; last two paragraphs on pg. 23; third paragraph on pg. 28) that the excitation light emitted from said at least one excitation light source is

coherent and is launched to said plurality of laterally separated measurement areas at the first diffraction order (*i.e.*, a resonance angle) for coupling into the waveguiding layer (*i.e.*, first optically transparent layer).

In regard to claim **27** which is dependent on claim 23, Neuschäfer *et al.* also disclose (third paragraph on pg. 28) that said at least one excitation light source is a plurality of coherent light sources of one of similar and different emission wavelengths.

In regard to claim **29** which is dependent on claim 23, Neuschäfer *et al.* also disclose (fourth paragraph on pg. 26) that said at least one detector is a laterally resolving detector from a group consisting of CCD cameras, CCD chips, photodiode arrays, avalanche diode allays, multichannel plates and multichannel photomultipliers.

In regard to claim **30** which is dependent on claim 23, Neuschäfer *et al.* also disclose (fourth paragraph on pg. 26) at least one optical component being located between at least one of said at least one excitation light source and said sensor platform and said sensor platform and said at least one detector, said at least one optical component comprising at least one of: a lens or a lens system operable to shape at least one of the excitation light and the one or more luminescences; a planar mirror or a curved mirror for deviation of at least one of the excitation light and the one or more luminescences; a prism for deviation of at least one of the excitation light and the one or more luminescences; a dichroic mirror for the spectrally selective deviation of parts of at least one of the excitation light and the one or more luminescences; a neutral density filter for regulation of light intensity of at least one of the excitation light and the one or more luminescences; an optical filter or a monochromator for spectrally selective

transmission of parts of at least one of the excitation light and the one or more luminescences; and a polarization selective element for selection of discrete polarization directions of at least one of the excitation light and the one or more luminescences.

In regard to claim **31** which is dependent on claim 23, Neuschäfer *et al.* also disclose (last paragraph on pg. 27) that said at least one excitation light source launches the excitation light in pulses with a duration of 1 ps to 100 s (*i.e.*, 1 fs to 10 min) and emission light from said plurality of laterally separated measurement areas is measured time-resolved.

In regard to claims **32** and **33** which are dependent on claim 23, Neuschäfer *et al.* also disclose (third paragraph on pg. 27) that said at least one detector measures light signals from at least one of the excitation light at a location of said at least one excitation light source, the excitation light after expansion, the excitation light after being multiplexed into individual beams, scattered excitation light from a location of one or more measurement areas of said plurality of laterally separated measurement areas, and the excitation light outcoupled by said grating structure beside said plurality of measurement areas for referencing purposes as a reference signal and that said one or more of said plurality of measurement areas for determination of the emission light and for the determination of the reference signal are the same.

In regard to claim **34** which is dependent on claim 23, Neuschäfer *et al.* also disclose (fourth paragraph on pg. 28) that said at least one excitation light source and

said at least one detector respectively launch the excitation light and detect the emission light from said plurality of laterally separated measurement areas sequentially for one or more measurement areas of said plurality of laterally separated measurement areas.

In regard to claim **35** which is dependent on claim 34, Neuschäfer *et al.* also disclose (fourth paragraph on pg. 28) that said sensor platform is operable to be moved between the sequential excitation and detection.

In regard to claims **37-39** which are dependent on claim 36, Neuschäfer *et al.* also disclose (first four paragraphs on pg. 14; second paragraph on pg. 26) at least one sample compartment (12) which is at least in the area of at least one laterally separated measurement area of said plurality of laterally separated measurement areas (1), wherein said at least one sample compartment (12) has a volume of 0.1 nL - 100  $\mu$ L (e.g., 28 mm by 6 mm by 0.2 mm or about 37  $\mu$ L), said at least one sample compartment (12) has an opening for supplying and/or removing samples or other reagents at a side opposite to the waveguiding layer (*i.e.*, first optically transparent layer), and said at least one sample compartment (12) being otherwise closed, and wherein the supplying and removing of the samples is performed in a closed flow through system.

In regard to claim **40** which is dependent on claim 37, Neuschäfer *et al.* also disclose (fifth paragraph on pg. 22; second and third paragraphs on pg. 24) that multi-step assays require multiple solutions. Thus the at least one sample compartment (see also fifth paragraph on pg. 39) is capable of accepting reagents (e.g., a luminescence-

labeled antibody) such that the reagents can be wetted during an assay for the determination of the one or more analytes and in contact with said at least one laterally separated measurement area.

In regard to claims **41**, **42**, **55**, **60**, and **62** in so far as understood, Neuschäfer *et al.* is applied as in claims 1, 23, 36, 56, 58, and 59 above.

In regard to claim **43** which is dependent on claim 41, Neuschäfer *et al.* also disclose (last paragraph on pg. 26 to second paragraph on pg. 27) simultaneously measuring at least one of isotropically emitted luminescence or luminescence that is coupled back into the first optically transparent layer and outcoupled by the grating structure.

In regard to claim **44** in so far as understood, Neuschäfer *et al.* is applied as in claims 17 and 41 above. Neuschäfer *et al.* also disclose (second and third paragraphs on pg. 1) that a fraction of the electromagnetic energy in the planar waveguide that enters the media of the lower refractive index is termed an evanescent field and (second paragraph on pg. 8) that sensitivity can be increase by using as strong an evanescent field as possible. Therefore sensitivity (*i.e.*, at least one of a dynamic range for signal measurement and a quantitative analyte determination) can be increased (or limited) by increasing (or limiting) the evanescent field which depends on the strength of the guided radiation intensity.

In regard to claim **45** which is dependent on claim 41 in so far as understood, Neuschäfer *et al.* also disclose (pg. 25) that one of a luminescent dye and a

nanoparticle is used as a luminescence label for generation of the luminescence, which can be excited and emits at a wavelength between 300 nm and 1100 nm.

In regard to claim **46** which is dependent on claim 45 in so far as understood, Neuschäfer *et al.* also disclose (first five paragraphs on pg. 22) that the luminescence label is bound to one of the one or more analytes, an analyte analogue in a competitive assay, and one of binding partners of the plurality of recognition elements or the plurality of recognition elements in a multi-step assay.

In regard to claim **47** which is dependent on claim 45 in so far as understood, Neuschäfer *et al.* also disclose (pg. 25) that at least one additional luminescence label is used.

In regard to claims **48** and **49** which are dependent on claim 47 in so far as understood, Neuschäfer *et al.* also disclose (pg. 25) that the second or more luminescence labels can be excited at the same wavelength as the first luminescence label, but emit at other wavelengths. It is inherent in excitation at the same wavelength and emission at other wavelengths that the excitation and emission spectra of the luminescence label and the at least one additional luminescence label are luminescent dyes that have excitation and emission spectra that do not or only partially overlap (see also separation of excitation light and luminescence with filters; fifth paragraph on pg. 26).

In regard to claim **50** which is dependent on claim 47 in so far as understood, Neuschäfer *et al.* also disclose (fourth paragraph on pg. 20) that the luminescence label and the at least one additional luminescence label are luminescent dyes and charge



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transfer or optical energy transfer from a first luminescent dye acting as a donor to a second luminescent dye acting as an acceptor is used for the detection of the one or more analytes.

In regard to claims **53** and **61** in so far as understood, Neuschäfer *et al.* is applied as in claim 41 above. Neuschäfer *et al.* also disclose (last paragraph on pg. 28 to second paragraph on pg. 29) simultaneously or sequentially determining one or more analytes from a group consisting of antibodies or antigens, receptors or ligands, chelators or histidine-tag components, oligonucleotides, DNA or RNA strands, DNA or RNA analogues, enzymes, enzyme cofactors or inhibitors, lectins and carbohydrates in one or more samples.

In regard to claim **54** which is dependent on claim 41 in so far as understood, Neuschäfer *et al.* also disclose (last paragraph on pg. 28 to second paragraph on pg. 29) that the one or more samples to be examined are naturally occurring body fluids from a group consisting of blood, serum, plasma, lymph, urine, and egg yolk, optically turbid liquids, surface water, soil extracts, plant extracts, bio- or process broths, or a substance taken from biological tissue.

### ***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 3 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neuschäfer *et al.* (WO 96/35940) in view of Fattinger (US 5,455,178).

In regard to claim 3 which is dependent on claim 1, while Neuschäfer *et al.* also disclose (fourth paragraph on pg. 17; fifth paragraph on pg. 28) that the grating structure comprises of plurality of coupling-in and coupling-out gratings having different grating constants (*i.e.*, periodicities) for the analysis of samples of different luminescence and that excitation of luminescence requires light sources of identical or different wavelengths, the system of Neuschäfer *et al.* lacks that the grating structure is a superposition of a plurality of grating structures for the incoupling of excitation light of different wavelengths. However, grating for the coupling of laser beams sources is well known in the art. For example, Fattinger teaches (Figs. 1-3) that gratings can be unidiffractive or multidiffractive (*i.e.*, superposition of two or more gratings) for light coupling. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a multidiffractive grating as the grating structure in

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the system of Neuschäfer *et al.*, in order to analyze samples of different luminescence which require excitation of luminescence with light sources of different wavelengths.

In regard to claim **28** which is dependent on claim 27, while Neuschäfer *et al.* also disclose (fourth paragraph on pg. 17; fifth paragraph on pg. 28) that the grating structure comprises of plurality of coupling-in and coupling-out gratings having different grating constants (*i.e.*, periodicities) for the analysis of samples of different luminescence and that excitation of luminescence requires light sources of identical or different wavelengths, the system of Neuschäfer *et al.* lacks that said grating structure is a superposition of a plurality of grating structures of different periodicities for the incoupling of excitation light of different wavelengths, and wherein said plurality of coherent light sources launch the excitation light either simultaneously or sequentially from different directions on said grating structure. However, grating for the coupling of laser beams sources is well known in the art. For example, Fettinger teaches (Figs. 1-3) that gratings can be unidiffractive or multidiffractive (*i.e.*, superposition of two or more gratings) for coupling of light from different directions. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a multidiffractive grating as the grating structure in the system of Neuschäfer *et al.*, in order to analyze samples of different luminescence which require luminescence excitation from different wavelength light sources located at different directions from the grating structure.

13. Claims 11 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neuschäfer *et al.* (WO 96/35940) in view of Rudigier *et al.* (US 5,738,825).

In regard to claim **11** which is dependent on claim 1, while Neuschäfer *et al.* also disclose (fourth paragraph on pg. 17; fifth paragraph on pg. 28) that the grating structure comprises of plurality of coupling-in and coupling-out gratings having different grating constants (*i.e.*, periodicities) for the analysis of samples of different luminescence and that excitation of luminescence requires light sources of identical or different wavelengths, the system of Neuschäfer *et al.* lacks that the grating structure has a laterally varying periodicity in parallel or perpendicular to the direction of propagation of the incoupled light in the waveguiding layer (*i.e.*, first optically transparent layer). However, grating for the coupling of laser beams sources is well known in the art. For example, Rudigier *et al.* teach (Fig. 5) that gratings for light coupling can have a laterally varying periodicity in parallel or perpendicular to the direction of propagation of the incoupled light. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a laterally varying periodicity grating as the grating structure in the system of Neuschäfer *et al.*, in order to analyze samples of different luminescence which require excitation of luminescence with light sources of different wavelengths.

In regard to claim **51** which is dependent on claim 41 in so far as understood, the method of Neuschäfer *et al.* lacks determining changes of an effective refractive index on the plurality of laterally separated measurement areas in addition to determining one or more analytes by luminescence. Rudigier *et al.* teach (column 1, lines 12-53) it is known in the art that binding of molecules to the waveguiding film changes the effective refractive index and thus the coupling condition. Inherent in changes in coupling

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condition is a change in the angle for maximum coupling of light to and from the waveguide which results in a change in the measured light intensity distribution.

Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention that binding of molecules to the waveguiding layer in the method of Neuschäfer *et al.* changes the effective refractive index and thus the coupling condition (*i.e.*, angle for maximum coupling) which is measured by a change in the luminescence intensity distribution.

14. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Neuschäfer *et al.* (WO 96/35940) in view of Sunagawa (US 5,101,459).

In regard to claim **18** which is dependent on claim 17, the system of Neuschäfer *et al.* lacks that said grating structure has a laterally varying grating depth in parallel with the direction of propagation of the incoupled excitation light. However, coupling of laser beams sources and waveguides is well known in the art. For example, Sunagawa teaches (column 3, lines 22-68) it is known in the art that the grating structure has a laterally varying grating depth in parallel to the direction of propagation of the incoupled excitation light in order to enhance coupling efficiency of laser beams sources and waveguides. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a laterally varying grating depth grating structure in the system of Neuschäfer *et al.*, in order to enhance coupling efficiency between laser beams sources and the waveguiding layer.

15. Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Neuschäfer *et al.* (WO 96/35940) in view of Groger *et al.* (US 5,577,137).

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In regard to claim **52** which is dependent on claim 41 in so far as understood, the method of Neuschäfer *et al.* lacks that at least one of said determining the one or more analytes by luminescence and determination of light signals at excitation wavelengths are performed as polarization-selective, and wherein one or more luminescences are measured at a polarization that is different from a polarization of the excitation light. Groger *et al.* teach (column 6, lines 42-50) that polarization-selective detection allows monitoring of fluorescence changes (such as amplification or quenching) resulting from the waveguide response to an analyte. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to perform polarization-selective detection in the method of Neuschäfer *et al.*, in order to monitor fluorescence changes (such as amplification or quenching) resulting from the waveguide response to an analyte as taught by Groger *et al.*

### ***Double Patenting***

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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17. Claims 1-62 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3, 12-18, 20-30, and 62 of copending Application No. 10/275,380 (US 2003/0138208 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the application define an invention that is merely an obvious variation of the invention claimed in copending Application No. 10/275,380.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Response to Arguments***

18. Applicant's arguments filed 6 January 2005 have been fully considered but they are not persuasive.

Applicant argues (third paragraph on pg. 21 to second paragraph on pg. 22 of remarks filed 6 January 2005) that absolutely none of the embodiments of Neuschäfer *et al.* discloses or suggests that the coupling-in grating 3 and/or the coupling-out grating 3' is continuously modulated over the complete area of the measurement areas. Examiner respectfully disagrees. Neuschäfer *et al.* state (third paragraph on pg. 8) that "... the waveguiding regions are provided ... with a common coupling-in grating ..." and (third paragraph on pg. 17) that "The gratings can be used both for coupling excitation light into the individual waveguiding layers and for coupling out luminiscence light backcoupled into the waveguiding layers". Thus Neuschäfer *et al.* disclose that the waveguiding regions are provided with a common grating used both for coupling excitation light into the individual waveguiding layers and

for coupling out luminiscence light backcoupled into the waveguiding layers. Therefore, Neuschäfer *et al.* teach a plurality of laterally separated measurement areas located on a first optically transparent layer is provided with a grating structure is continuously modulated over a complete of said plurality of laterally separated measurement areas.

Applicant argues (third paragraph on pg. 22 to third paragraph on pg. 24 of remarks filed 6 January 2005) that not all out-coupling gratings prevent cross-talk. Examiner respectfully disagrees. The function of an out-coupling grating is to couple out the light. Thus light removed (*i.e.*, out-coupled) by an out-coupling grating is not available to cause cross-talk. Therefore, all out-coupling gratings prevent cross-talk since an out-coupling grating removes the light which would have caused cross-talk.

### ***Conclusion***

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shun Lee whose telephone number is (571) 272-2439. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Porta can be reached on (571) 272-2444. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SL

  
CONSTANTINE HANNAFER  
PRIMARY EXAMINER